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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,068	10/23/2003	Graham Sommer	STFUP145/S03-109	2220
58766	7590	10/16/2009		
Beyer Law Group LLP P.O. BOX 1687 Cupertino, CA 95015-1687			EXAMINER LAMPRECHT, JOEL	
			ART UNIT 3737	PAPER NUMBER
			NOTIFICATION DATE 10/16/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOmail@beyerlaw.com

Office Action Summary

Application No.

10/693,068

Applicant(s)

SOMMER, GRAHAM

Examiner

JOEL M. LAMPRECHT

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/12/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katzberg et al (6,122,540) in view of Unger (US 6,071,494). Katzberg et al disclose a method of imaging targeted tissues of the body via contrast enhancement for comparative analysis and renal function assessment from an extraction fraction (Col 1 Line 65-Col 2 Line 17). Katzberg et al disclose imaging arterial blood before addition of contrast (Col 2 Line 55-65), administration of contrast (Col 2 Line 42-55), and comparative imaging of both arterial and venous blood after the administration of contrast to provide an assessment of renal function through an analysis of the extraction or filtration rate of the contrast (Col 3 Line 1-Col 4 Line 40). The methods of Katzberg et al provide images based on the fractions of contrast in the blood of both the arteries and veins of the kidneys by analyzing the images provided by the MR measurements (Col 3 Line 1-27 Col 3 Line 60-Col 4 Line 3).

Katzberg et al do not disclose the specific use of iohexol or iothalamate, nor do they describe a measurement of renal extraction fraction based on *CT number* of corresponding images which are acquired. Attention is directed to the secondary reference by Unger which discloses in detail renal function methods involving Gd-DTPA

and discloses the knowledge of iodine preparations for CT specific image analysis (The remainder of the chemical composition is disclosed in their discussion on tagging molecules and volatile components) (Col 2 Line 35-Col 3 Line 5) and they make reference to US 5,205,290 for a description of analysis of CT number as relates to analysis of any CT image (specifically those with contrast agents, Col 2 Line 35-50). Additionally Unger discloses a method of blood-based analysis of contrast agent concentration through comparative analysis of blood before, during and after administration of a contrast agent (Col 12 Line 60-Col 13 Line 53, Col 50 Line 65- Col 51 Line 25, Col 51 Line 58-64, Col 56 Line 35-Col 58 Line 20 for quantitative analysis). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the analysis techniques and further contrast agents disclosed by Unger with the methods described by Katzberg et al for the purpose of providing a CT analysis of a variation in renal function and further diagnosis of renal diseases or variations.

Response to Arguments

Applicant's arguments filed 6/12/09 have been fully considered but they are not persuasive. With regard to the argument that MRI applications of Katzberg et al, including imaging before and after addition of contrast, comparative analysis of images acquired with radiographic contrast (including Gd-DTPA), as well as arterial and renal comparisons to acquire filtration fractions for the blood, are not wholly analogous to those used with CT, Examiner respectfully disagrees. CT number is a normalized value of x-ray absorption, typically in Hounsfield units or represented by a Hounsfield number (HU), and is calculated in a very similar manner to T-1 absorption in MRI, in particular

with methods including Gd-DTPA. Unger is used as the teaching reference because of the particular teaching of HU's relationship to Gd-DTPA so as to provide both motivation and a method for use of Gd-DTPA with CT methodology (See Col 10 Line 5-Col 11 Line 15, Col 12 Line 25-Col 13 Line 13 of Unger) where diagnostic imaging methodologies are linked with respect to renal function assessments.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JOEL M. LAMPRECHT** whose telephone number is (571)272-3250. The examiner can normally be reached on 8:30-5:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML

/BRIAN CASLER/

Supervisory Patent Examiner, Art Unit 3737